

Claims 1, 2-15, 18, 19 and 20 stand rejected under 35 USC 103(a) as obvious over U.S. Patent 4,931,285 (Edgren) in view of U.S. Patent 6,024,982 (Oshlack), U.S. Patent 5,455,046 (Baichwal) and U.S. Patent 5,681,584 (Savastano). That rejection respectfully is traversed.

Firstly, it is noted that Edgren describes coating the drug core with polymeric materials that are cellulose based, such as cellulose acetate, (see col. 4, lines 65-68 and col. 5, lines 1-14). This is the subcoat or inner coat of Edgren. The outer coat is described as being prepared from hydroxypropyl cellulose, methyl cellulose, methylethylcellulose, polyvinylpyrrolidone, sodium carboxymethyl cellulose and hydroxypropylmethyl cellulose. In contrast, Applicants' inner membrane comprises a polyalkylcellulose such as poly(ethylcellulose) and the outer membrane comprises cellulose based polymers such as cellulose acylate, cellulose diacylate and cellulose triacylate. Thus, the compositions utilized by Edgren for the subcoat (inner membrane) and overcoat (exterior membrane), respectively, are reversed from the polymeric compositions for the inner membrane and exterior membrane of the present invention. Because of this reversal, Edgren is considered fatally defective as a reference with respect to the present invention. No combination of Edgren as the primary reference with the secondary references cited will render the invention obvious because it is not apparent from any of the references to reverse the membranes of Edgren and arrive at Applicants' invention. Accordingly, because of the deficiencies in Edgren, it is submitted that the Office has not met its burden of demonstrating a case of *prima facie* obviousness.

In addition, the disclosure of the combination of zein in an ethylcellulose coating by Oshlack is of no moment. First, zein is not used in Applicants' invention in the inner membrane that is formed of an alkyl-cellulose. Instead, zein is used in the exterior membrane formed of the cellulose ester polymer, cellulose ether polymer and cellulose ester-ether polymer. Thus, even if there was some motivation to combine Edgren with Oshlack, which appears totally absent, that combination would not teach or suggest the present claim limitations. What motivation is there in Edgren or Oshlack for their combination? Surely the mere identification of components is not enough, especially when the combination of components described in the reference is not consistent with the component combinations of the present invention. In short, then, there is none.

Also, Oshlack is directed to a sustained release tablet formed of an immediate release core that is coated with a film through which drug can diffuse over time. In contrast, the membranes of Edgren are impermeable to the passage of drug. One skilled in the art would not look to Oshlack if making modifications to Edgren since the two delivery systems are very different.

A similar analysis can be made of the relevance of Baichwal. Baichwal notes the existence of osmotic systems for delivery of drug (see col. 1, lines 42-50). In particular, Baichwal notes that the semipermeable wall "is substantially impermeable to drug." Baichwal does not suggest modifying the membranes of Edgren. Instead, Baichwal formulates a composition containing sustained release excipients (gelling agents) and drug. Baichwal's disclosure of ethyl cellulose as a coating material adds nothing to Edgren, since Edgren already discloses alkyl celluloses as coating materials. Thus, Baichwal's disclosure of the use of ethyl cellulose with coated tablets is not enough to provide the requisite motivation to modify Edgren in a manner such that one skilled in the art would arrive at the instant invention. Baichwal's statements are nothing more than a material listing of known polymers that are useful for coatings. Nothing in Baichwal or Edgren suggests the selection of a particular polymer for a particular membrane to arrive at the instant invention.

It is submitted further that the disclosures of Edgren and Savastano also do not suggest their combination. The inner membrane of Sevastano is a delay jacket, which prevents fluid from reaching the drug core for a limited period of time to delay release of the active agent. Such is not the case with the inner membrane or subcoat of Edgren, which is not intended to delay release of active agent. Thus, the combination of the references is considered improper.

Simply stated, the only motivation for picking the particular components of Edgren, Oshlack, Baichwal and Savastano and interchanging or combining them appears to be that provided by Applicants' disclosure of the invention. However, use of Applicants' disclosure to provide the motivation for such selection is not permissible. Accordingly, there is no case of *prima facie* obviousness presented and the rejection should be withdrawn.

Finally, even if one ignored the foregoing and the combination of references was made, their combined disclosures do not teach or suggest all of the limitations of the claims. In particular, they do not teach the respective compositions of the inner

and outer membranes as claimed. Furthermore, they do not teach or suggest the specific limitations with respect to the amounts of the various components of the compositions that are included in the claims.

Thus, a *prima facie* case for obviousness has not been made and the rejection should be withdrawn.

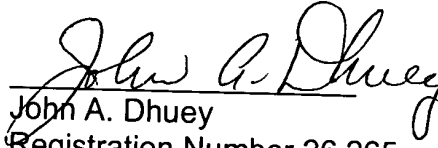
Reconsideration and allowance of claims 1, 2, 5-15 and 18-20 is solicited

A copy of the claims as amended is attached hereto.

Respectfully submitted,

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